

REMARKS

Upon amendment, Claims 1-11 are pending in this application. Claim 1 has been amended to recite “or a pharmaceutically acceptable salt or stereoisomer thereof.” In particular, support for the amendments can be found throughout the specification and claims as originally filed. No new matter has been added.

Applicants respectfully reserve the right to pursue any non-elected, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

Reconsideration and withdrawal of the objections to and the rejections of this application in view of the amendments and remarks herewith, is respectfully requested, as the application is in condition for allowance.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-7 and 9-11 are rejected under 35 U.S.C. 112, First Paragraph, as allegedly failing to comply with the enablement requirement, particularly with respect to the enablement of solvates or solvates of a salt. While Applicants strongly disagree with the Examiner’s allegation, and solely for the purpose of advancing prosecution, Claim 1 has been amended to recite only “pharmaceutically acceptable salt or stereoisomer thereof” instead of “pharmaceutically acceptable salt, solvate, solvate of a salt, or stereoisomer thereof.” No new matter has been added by this amendment.

Claims 10 and 11 are further rejected under 35 U.S.C. 112, First Paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Office Action alleges that “the instant claims, as recited, are reach through claims.” Applicants respectfully disagree.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). The

examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *Manual of Patent Examining Procedure* ("MPEP") § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)).

Accordingly:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as being in compliance with the enablement requirement* ... unless there is a *reason to doubt the objective truth of the statements* contained therein which must be relied on for enabling support

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It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Id. (emphases added).

Applicants respectfully submit that whether or not the scope of a claim is broad is irrelevant to the assessment of the enablement of the claim. The question is whether those skilled in the art would have been able to make and use the claimed invention based on the disclosure. (*See U.S. v. Telecommunications, Inc.*, at 785).

Applicants respectfully submit that the pending claims are enabled because the specification "contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented." *Id.*

For example, the specification teaches "the utility of the compounds of the present invention can be illustrated, for example, by their activity *in vitro* in the *in vitro* tumor cell proliferation assay described" and that "the link between activity in tumor cell proliferation

assays *in vitro* and anti-tumor activity in the clinical setting has been well established in the art.

For example, the therapeutic utility of taxol (Silvestrini; et al. Stem Cells 1993, 11(6), 528-35), taxotere (Bissery et al. Ant Cancer Drugs 1995, 6(3), 339), and topoisomerase inhibitors (Edelman et al. Cancer Chemother. Pharmacol. 1996, 37(5), 385-93) was demonstrated with the use of *in vitro* tumor proliferation assays." (Page 31, line 29 – Page 32, line 2).

Similarly, it is disclosed that the claimed compounds can be prepared by synthetic procedures described in the scheme presented on Pages 40-48 and in the Examples.

Finally, the specification discloses various tests and assays which can be readily performed by one of ordinary skill in the art to determine the desired activity without undue experimentation (Pages 246-247). Therefore, it is clear that a sufficient guidance is provided in the specification so as to allow those of ordinary skill in the art to make and use the claimed invention, as required by 35 U.S.C. § 112, first paragraph.

To the extent that any assays provided herein are prophetic, Applicants point out that the specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).

Nevertheless, Applicants respectfully assert that sufficient guidance is provided in the specification so as to allow those of ordinary skill in the art to make and use the claimed invention. Indeed, the claimed invention is directed to the use of obtainable compounds. The skilled artisan can readily determine the activity for any of the compounds encompassed by the claims by using the assays described in the specification, which can be readily used to determine that a synthesized compound is useful in the treatment of the diseases recited in the claims. Moreover, the determination by a physician as to whether a claimed compound is effective in treating a recited disease in a given patient is a type of determination that is always made by physicians for every

pharmaceutical. Indeed, the determination is a routine one that every physician is prepared to make, and which requires little or no effort. Therefore, Applicants respectfully submit that one reasonably skilled in the art could make or use the invention as claimed without undue experimentation.

In sum, Applicants respectfully submit that: (1) the specification provides sufficient information and guidance to those of ordinary skill in the art to make and use the claimed invention; (2) the Examiner did not provide any factual or legal basis to doubt that the claims are enabled; and (3) to the extent any experimentation is necessary, such experimentation is not undue. Therefore, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Applicants respectfully request that the rejections of the claims under 35 U.S.C. § 112, First Paragraph be reconsidered and withdrawn.

Obviousness-type Double Patenting

Claims 1-14 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting over claims 1-11 of copending Application Serial No. 10/573,227.

As it remains unknown what subject matter claimed and disclosed in the present application will be deemed allowable; any statement regarding the provisional rejection made on Applicants' part is premature. Therefore, Applicants respectfully traverse this rejection, and request that this rejection be held in abeyance until subject matter is deemed allowable in this application.

CONCLUSION

In view of the amendments and remarks made herein, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested.

Applicants have submitted a petition for an extension of time herewith, but believe that no additional fees are required for consideration and entry of this paper. However, Applicants authorize the Director to charge any required fee or credit any overpayment to Deposit Account No. 04-1105, under Order No. 67322(303981).

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